

109TH CONGRESS
2D SESSION

S. _____

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to improve drug safety and oversight, and for other purposes.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

A BILL

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to improve drug safety and oversight, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Enhancing Drug Safe-
5 ty and Innovation Act of 2006”.

1 **TITLE I—RISK EVALUATION AND**
2 **MITIGATION STRATEGIES**

3 **SEC. 101. RISK EVALUATION AND MITIGATION STRATEGIES.**

4 Section 505 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 355) is amended by adding at the end the
6 following:

7 “(o) RISK EVALUATION AND MITIGATION STRAT-
8 EGY.—

9 “(1) IN GENERAL.—In the case of any drug,
10 except a vaccine or a blood product, subject to sub-
11 section (b) or (j) or section 351 of the Public Health
12 Service Act for which a risk evaluation and mitiga-
13 tion strategy is approved as provided for in this sub-
14 section, the applicant shall comply with the require-
15 ments of such strategy, which—

16 “(A) shall require the minimal elements re-
17 quired under paragraph (2); and

18 “(B) may require—

19 “(i) one or more goals to evaluate or
20 mitigate a serious risk listed in the labeling
21 of the drug or to identify unexpected seri-
22 ous risks of the drug; and

23 “(ii) additional elements under para-
24 graph (3) or (4), as necessary, taking into
25 consideration such goals, to communicate

1 about, assess, or manage a serious risk
2 listed in the labeling of the drug or to
3 identify or assess serious unexpected risks.

4 “(2) REQUIRED ELEMENTS OF A RISK EVALUA-
5 TION AND MITIGATION STRATEGY.—A risk evalua-
6 tion and mitigation strategy shall require the fol-
7 lowing elements—

8 “(A) labeling for the drug for use by
9 health care providers;

10 “(B) submission of reports for the drug re-
11 quired under subsection (k);

12 “(C) a surveillance plan, that includes a
13 delineation of the role of the applicant and the
14 Secretary, to assess further any serious risk
15 listed in the labeling of the drug and to iden-
16 tify, as appropriate, any unexpected serious risk
17 of the drug, considering—

18 “(i) the number of patients who are
19 expected to use the drug or, if the drug is
20 approved, who are estimated to be using
21 the drug, and their expected or observed
22 comorbidities;

23 “(ii) the seriousness of the underlying
24 disease or condition that the drug is used
25 to treat;

1 “(iii) the expected or actual duration
2 of treatment with the drug;

3 “(iv) the availability of a comparator
4 drug or other treatment, if any, for such
5 disease and condition; and

6 “(v) the seriousness of the risk at
7 issue and its background incidence in the
8 population; and

9 “(D) a timetable for submission of assess-
10 ments of the strategy, which shall be no less
11 frequently than once annually for the first 3
12 years after the drug is initially approved under
13 subsection (c) or licensed under section 351 of
14 the Public Health Service Act.

15 “(3) ADDITIONAL POTENTIAL ELEMENTS OF A
16 RISK EVALUATION AND MITIGATION STRATEGY.—To
17 communicate about, assess, or manage a serious risk
18 listed in the labeling of the drug, or to identify or
19 assess an unexpected serious risk of the drug, the
20 risk evaluation and mitigation strategy for the drug
21 may require that—

22 “(A) the applicant develop nonpromotional
23 labeling that is written in nontechnical, under-
24 standable language for patients (to be made
25 available at the discretion of the applicant to

1 health care providers, pharmacists, and pa-
2 tients) if, with respect to such drug, the Sec-
3 retary determines that such labeling may
4 help—

5 “(i) assure the effectiveness of the
6 drug; or

7 “(ii) minimize a serious risk listed in
8 the labeling of the drug;

9 “(B) the applicant develop a Medication
10 Guide, as provided for under part 208 of title
11 21, Code of Federal Regulations (or any suc-
12 cessor regulations), for distribution to each pa-
13 tient when the drug is dispensed;

14 “(C) the applicant conduct a communica-
15 tion plan to physicians, if, with respect to such
16 drug, the Secretary determines that such plan
17 may support implementation of an element of
18 the strategy under subparagraph (D), (E), or
19 (F) or under paragraph (4), which may in-
20 clude—

21 “(i) letters to health care providers;

22 “(ii) information to educate health
23 care providers about the elements of the
24 risk evaluation and mitigation strategy and
25 encourage their compliance with compo-

1 nents that apply to such health care pro-
2 viders, or to explain certain safety proto-
3 cols (such as screening and monitoring); or

4 “(iii) educating health care providers
5 through professional societies about any
6 serious risks of the drug and how to pre-
7 scribe and use the drug safely;

8 “(D) the applicant include a black box
9 warning in the labeling of the drug about a se-
10 rious risk of the drug;

11 “(E) the applicant or the Secretary con-
12 duct an appropriate post-approval study of the
13 drug (with target commencement and comple-
14 tion dates) to assess an empirical signal of a se-
15 rious risk with use of the drug or to screen for
16 serious risks in domestic populations who may
17 use the drug but were not included in studies
18 used to approve the drug (such as older people,
19 people with comorbidities, pregnant women, or
20 children), such as a prospective or retrospective
21 observational study using—

22 “(i) a large database derived from
23 medical care systems;

24 “(ii) a voluntary registry;

25 “(iii) case controls; or

1 “(iv) cohorts;

2 “(F) for a drug for which there is no effec-
3 tive approved application under subsection (j)
4 as of the date that the requirement is first im-
5 posed, the applicant conduct an appropriate
6 post-approval clinical trial of the drug (with
7 target commencement and completion dates), to
8 be included in the clinical trial registry data-
9 base and clinical trial results database provided
10 for under section 402(j) of the Public Health
11 Service Act, if the Secretary determines that
12 the clinical trial is necessary, and that a study
13 under subparagraph (E) will likely be inad-
14 equate, to assess an empirical signal of a seri-
15 ous risk with use of the drug (which shall not
16 include a risk that is merely biologically plau-
17 sible) derived from—

18 “(i) a clinical trial;

19 “(ii) adverse event reports;

20 “(iii) a post-approval study, including
21 a study under subparagraph (E); or

22 “(iv) peer-reviewed literature;

23 “(G) the applicant submit to the Secretary
24 advertisements of the drug for preclearance, if
25 the Secretary determines that such clearance is

1 necessary to ensure compliance with section
2 502(n) with respect to the disclosure of infor-
3 mation about a serious risk listed in the label-
4 ing of the drug;

5 “(H) the applicant include a specific dis-
6 closure in advertisements of the drug, if the
7 Secretary determines that advertisements lack-
8 ing such disclosure would be false or misleading
9 or that such disclosure is necessary to protect
10 public health and safety—

11 “(i) of the date the drug was ap-
12 proved and that the data used to approve
13 the drug, and the information collected
14 since approval of the drug, may not have
15 identified all significant, serious risks of
16 using the drug;

17 “(ii) about a serious risk listed in the
18 labeling of the drug; or

19 “(iii) about a protocol to ensure safe
20 use described in the labeling of the drug;
21 or

22 “(I) for a fixed period after initial ap-
23 proval, not to exceed 2 years, the applicant not
24 issue or caused to be issued direct-to-consumer
25 advertisements of the drug, if the Secretary de-

1 termines that such prohibition is necessary to
2 protect public health and safety while additional
3 information about serious risks of the drug is
4 collected, considering—

5 “(i) the number of patients who may
6 be treated with the drug;

7 “(ii) the seriousness of the condition
8 for which the drug will be used;

9 “(iii) the serious risks listed in the la-
10 beling of the drug;

11 “(iv) whether there are other ap-
12 proved drugs in the pharmacological class
13 of the drug or with the same intended use
14 as the drug; and

15 “(v) the extent to which studies used
16 to approve the drug were insufficiently sta-
17 tistically powered to identify potential seri-
18 ous risks of the drug that might occur in
19 significant numbers among the patients ex-
20 pected to be treated with the drug.

21 “(4) RESTRICTIONS ON DISTRIBUTION AND
22 USE.—

23 “(A) IN GENERAL.—If the Secretary deter-
24 mines that a drug presents a substantial risk to
25 public health, the risk evaluation and mitigation

1 strategy may also require restrictions on dis-
2 tribution and use to address such risk of the
3 drug, as long as such restrictions are—

4 “(i) commensurate with the risk;

5 “(ii) necessary to ensure safe use of
6 the drug given the risk; and

7 “(iii) not unduly burdensome on pa-
8 tient access to the drug.

9 “(B) ELEMENTS.—The restrictions on dis-
10 tribution and use described under subparagraph
11 (A) may require that—

12 “(i) health care providers that pre-
13 scribe the drug have particular training or
14 experience, or elect to be specially certified;

15 “(ii) pharmacies, practitioners, or
16 health care settings that dispense the drug
17 be specially certified;

18 “(iii) the drug be dispensed to pa-
19 tients with evidence or other documenta-
20 tion of safe-use conditions, such as labora-
21 tory test results;

22 “(iv) each patient using the drug be
23 subject to certain monitoring; or

24 “(v) each patient using the drug be
25 enrolled in a registry.

1 “(C) COMPLIANCE SYSTEM.—The restric-
2 tions on distribution and use described under
3 subparagraph (A) shall require a compliance
4 system through which the applicant shall—

5 “(i) monitor and evaluate compliance
6 with the restrictions by health care pro-
7 viders, pharmacists, patients, and other
8 parties in the health care system who are
9 responsible for implementing the restric-
10 tions;

11 “(ii) work to increase adherence to
12 the restrictions by health care providers,
13 pharmacists, patients, and other parties in
14 the health care system who are responsible
15 for implementing the restrictions; and

16 “(iii) prohibit participation by those
17 health care providers, pharmacists, and
18 other parties in the health care system—

19 “(I) who are responsible for im-
20 plementing the restrictions; and

21 “(II) whom the applicant knows
22 have failed to meet their responsibil-
23 ities for implementing the restrictions.

24 “(5) SUBMISSION AND REVIEW OF RISK EVAL-
25 UATION AND MITIGATION STRATEGY.—

1 “(A) PROPOSED RISK EVALUATION AND
2 MITIGATION STRATEGY.—An applicant shall in-
3 clude in an application, except in an application
4 for a vaccine or blood product, under subsection
5 (b) or section 351 of the Public Health Service
6 Act (including in a supplemental application
7 seeking a new indication if no risk evaluation
8 and mitigation strategy for the drug is in effect
9 under this subsection) a proposed risk evalua-
10 tion and mitigation strategy, which—

11 “(i) shall include the minimal ele-
12 ments required under paragraph (2); and

13 “(ii) may also include additional ele-
14 ments as provided for under paragraphs
15 (3) and (4).

16 “(B) ASSESSMENT AND MODIFICATION OF
17 A RISK EVALUATION AND MITIGATION STRAT-
18 EGY.—

19 “(i) IN GENERAL.—The applicant may
20 submit an assessment of, and propose a
21 modification to, the approved risk evalua-
22 tion and mitigation strategy for a drug at
23 any time, and shall submit such an assess-
24 ment, which may propose such a modifica-
25 tion—

1 “(I) when submitting a supple-
2 mental application for a new indica-
3 tion under subsection (b) or section
4 351 of the Public Health Service Act;

5 “(II) when required by the strat-
6 egy, as provided for in the timetable
7 under paragraph (2)(D);

8 “(III) within a time specified by
9 the Secretary, not to be less than 45
10 days, when ordered by the Secretary if
11 the Secretary determines that new in-
12 formation indicates that an element
13 under paragraph (2) or (3) should be
14 modified or included in the strategy;

15 “(IV) within 90 days when or-
16 dered by the Secretary if the Sec-
17 retary determines that new informa-
18 tion indicates that an element under
19 paragraph (4) should be modified or
20 included in the strategy; or

21 “(V) within 15 days when or-
22 dered by the Secretary if the Sec-
23 retary determines that there may be a
24 cause for action by the Secretary
25 under subsection (e).

1 “(ii) ASSESSMENT.—An assessment of
2 the performance and adequacy of the ap-
3 proved risk evaluation and mitigation
4 strategy for a drug shall include—

5 “(I) with respect to any goal for
6 the strategy, an assessment of wheth-
7 er the strategy is meeting the goal or
8 whether the goal should be modified;

9 “(II) with respect to any post-ap-
10 proval study required under para-
11 graph (3)(E), the status of such
12 study, the expected completion date,
13 and whether any difficulties com-
14 pleting the study have been encoun-
15 tered; and

16 “(III) with respect to any post-
17 approval clinical trial required under
18 paragraph (3)(F), whether enrollment
19 has begun, the number of participants
20 enrolled, the expected completion date,
21 and whether any difficulties com-
22 pleting the study have been encoun-
23 tered.

24 “(iii) MODIFICATION.—A modification
25 (whether an enhancement or a reduction)

1 to the approved risk evaluation and mitiga-
2 tion strategy for a drug may include the
3 addition or modification of any element
4 under paragraph (2) or the addition, modi-
5 fication, or removal of any element under
6 paragraph (3) or (4), such as—

7 “(I) a labeling change;

8 “(II) adding a post-approval
9 study or clinical trial requirement;

10 “(III) modifying a post-approval
11 study or clinical trial requirement
12 (such as a modification due to legiti-
13 mate difficulties recruiting partici-
14 pants);

15 “(IV) adding, modifying, or re-
16 moving a restriction on distribution or
17 use; or

18 “(V) modifying the timetable for
19 assessments of the strategy under
20 paragraph (2)(D), including to reduce
21 the frequency of assessments, or re-
22 move the requirements for periodic as-
23 sessments, if the Secretary determines
24 that the serious risks, if any, of the

1 drug have been adequately identified,
2 assessed, and managed.

3 “(C) REVIEW.—The Secretary shall
4 promptly review the proposed risk evaluation
5 and mitigation strategy for a drug submitted
6 under paragraph (A), or an assessment of the
7 approved risk evaluation and mitigation strat-
8 egy for a drug submitted under subparagraph
9 (B).

10 “(D) DISCUSSION.—The Secretary shall
11 initiate discussions of the proposed risk evalua-
12 tion and mitigation strategy for a drug sub-
13 mitted under subparagraph (A), or of an as-
14 sessment of the approved risk evaluation and
15 mitigation strategy for a drug submitted under
16 subparagraph (B), with the applicant to nego-
17 tiate a mutually agreeable strategy—

18 “(i) when submitted as part of an ap-
19 plication or supplemental application under
20 subparagraph (A) or (B)(i)(I), not less
21 than 60 days before the action deadline for
22 the application that has been agreed to by
23 the Secretary and that has been set forth
24 in goals identified in letters of the Sec-
25 retary (relating to the use of fees collected

1 under section 736 to expedite the drug de-
2 velopment process and the review of
3 human drug applications);

4 “(ii) when submitted under subpara-
5 graph (B)(i)(II) or (III), not later than 20
6 days after such submission;

7 “(iii) when submitted voluntarily by
8 the applicant or under subparagraph
9 (B)(i)(IV), not later than 30 days after
10 such submission; or

11 “(iv) when submitted under subpara-
12 graph (B)(i)(V), not later than 10 days
13 after such submission.

14 “(E) ACTION.—Unless the applicant re-
15 quests the dispute resolution process described
16 under subparagraph (F), the Secretary shall
17 approve and describe the risk evaluation and
18 mitigation strategy for a drug, or any modifica-
19 tion to the strategy—

20 “(i) as part of the action letter on the
21 application, when a proposed strategy is
22 submitted under subparagraph (A) or an
23 assessment of the strategy is submitted
24 under subparagraph (B)(i)(I); or

1 “(ii) in an order, which shall be made
2 public, issued not later than 50 days after
3 the date discussions of such modification
4 begin under subparagraph (C), when an
5 assessment of the strategy is submitted
6 voluntarily by the applicant or under sub-
7 clause (II), (III), (IV), or (V) of subpara-
8 graph (B)(i).

9 “(F) DISPUTE RESOLUTION.—

10 “(i) REQUEST FOR REVIEW.—Not
11 earlier than 20 days, and not later than 45
12 days, after discussions under subparagraph
13 (D) have begun to negotiate a mutually
14 agreeable risk evaluation and mitigation
15 strategy, the applicant may request in
16 writing that a dispute about the strategy
17 be reviewed by the Drug Safety Oversight
18 Board.

19 “(ii) SCHEDULING REVIEW.—If the
20 applicant requests review under clause (i),
21 the Secretary shall schedule the dispute for
22 review at 1 of the next 2 regular meetings
23 of the Drug Safety Oversight Board,
24 whichever meeting date is more prac-
25 ticable, or the Secretary may convene a

1 special meeting of the Drug Safety Over-
2 sight Board to review the matter more
3 promptly.

4 “(iii) AGREEMENT TERMINATES DIS-
5 PUTE RESOLUTION.—At any time before a
6 decision and order is issued under clause
7 (vi), the Secretary and the applicant may
8 reach an agreement on the risk evaluation
9 and mitigation strategy, terminating the
10 dispute resolution process, and the Sec-
11 retary shall issue an action letter or order,
12 as appropriate, that describes the mutually
13 agreeable strategy.

14 “(iv) MEETING OF THE BOARD.—At
15 the meeting of the Drug Safety Oversight
16 Board described in clause (ii), the Board
17 shall—

18 “(I) hear from both parties; and

19 “(II) review the dispute.

20 “(v) RECOMMENDATION OF THE
21 BOARD.—No later than 5 days after such
22 meeting of the Drug Safety Oversight
23 Board, the Board shall provide a written
24 recommendation on resolving the dispute
25 to the Secretary.

1 “(vi) ACTION BY THE SECRETARY.—

2 “(I) ACTION LETTER.—With re-
3 spect to a proposed risk evaluation
4 and mitigation strategy submitted
5 under subparagraph (A) or to an as-
6 sessment of the strategy submitted
7 under subparagraph (B)(i)(I), the
8 Secretary shall issue an action letter
9 that resolves the dispute not later
10 than the later of—

11 “(aa) the action deadline re-
12 ferred to in subparagraph (D)(i);
13 or

14 “(bb) 7 days after receiving
15 the recommendation of the Drug
16 Safety Oversight Board.

17 “(II) ORDER.—With respect to
18 an assessment of the risk evaluation
19 and mitigation strategy submitted vol-
20 untarily by the applicant or under
21 subclause (II), (III), (IV), or (V) of
22 subparagraph (B)(i), the Secretary
23 shall issue an order, which shall be
24 made public, that resolves the dispute
25 not later than 7 days after receiving

1 the recommendation of the Drug Safe-
2 ty Oversight Board.

3 “(vii) EFFECT ON ACTION DEAD-
4 LINE.—With respect to the application or
5 supplemental application in which a pro-
6 posed risk evaluation and mitigation strat-
7 egy is submitted under subparagraph (A)
8 or in which an assessment of the strategy
9 is submitted under subparagraph (B)(i)(I),
10 the Secretary shall be considered to have
11 met the action deadline referred to in sub-
12 paragraph (D)(i) with respect to such ap-
13 plication if the applicant requests the dis-
14 pute resolution process described in this
15 subparagraph and if the Secretary—

16 “(I) has initiated the discussions
17 described under such subparagraph
18 not less than 60 days before such ac-
19 tion deadline; and

20 “(II) has complied with the tim-
21 ing requirements of scheduling review,
22 providing a written recommendation,
23 and issuing an action letter under
24 clauses (ii), (v), and (vi), respectively.

1 “(G) PROCESS FOR ADDRESSING DRUG
2 CLASS EFFECTS.—

3 “(i) IN GENERAL.—When a concern
4 about a serious risk of a drug may be re-
5 lated to the pharmacological class of the
6 drug, the Secretary may defer assessments
7 of the approved risk evaluation and mitiga-
8 tion strategies for such drugs until the
9 Secretary has convened, after appropriate
10 public notice, one or more public meetings
11 to consider possible responses to such con-
12 cern.

13 “(ii) PUBLIC MEETINGS.—Such public
14 meetings may include—

15 “(I) one or more meetings of the
16 applicants for such drugs;

17 “(II) one or more meetings of an
18 appropriate scientific advisory com-
19 mittee; and

20 “(III) one or more workshops of
21 scientific experts and other stake-
22 holders.

23 “(iii) ACTION.—After considering the
24 discussions from any meetings under
25 clause (ii), the Secretary may—

1 “(I) announce in the Federal
2 Register a planned regulatory action,
3 including a modification to each risk
4 evaluation and mitigation strategy, for
5 drugs in the pharmacological class;

6 “(II) seek public comment about
7 such action; and

8 “(III) after seeking such com-
9 ment, issue an order addressing such
10 regulatory action.

11 “(H) INTERNATIONAL COORDINATION.—

12 To the extent practicable, the Secretary shall
13 coordinate elements of the risk evaluation and
14 mitigation strategy for a drug, such as the
15 timetable for submission of assessments under
16 paragraph (2)(D), a study under paragraph
17 (3)(E), or a clinical trial under paragraph
18 (3)(F), with efforts to manage the serious risks
19 of the drug by the marketing authorities of
20 other countries whose drug approval and risk
21 management processes the Secretary deems
22 comparable to the drug approval and risk man-
23 agement processes of the United States.”.

1 **SEC. 102. ENFORCEMENT.**

2 (a) MISBRANDING.—Section 502 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
4 ed by adding at the end the following:

5 “(x) If it is a drug subject to an approved risk evalua-
6 tion and mitigation strategy under section 505(o) and the
7 applicant for such drug fails to—

8 “(1) make a labeling change required by the
9 Secretary after the Secretary has completed review
10 of, and acted on, an assessment of such strategy
11 under paragraph (5) of such section; or

12 “(2) comply with a requirement of such strat-
13 egy with respect to advertising as provided for under
14 subparagraph (G), (H), or (I) of paragraph (3) of
15 such section.”.

16 (b) CIVIL PENALTIES.—Section 303(f) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is
18 amended—

19 (1) by redesignating paragraphs (3), (4), and
20 (5) as paragraphs (4), (5), and (6), respectively;

21 (2) by inserting after paragraph (2) the fol-
22 lowing:

23 “(3) An applicant (as such term is used in sec-
24 tion 505(o)) who knowingly fails to comply with a
25 requirement of an approved risk evaluation and miti-
26 gation strategy under such section 505(o) shall be

1 subject to a civil money penalty of not less than
2 \$15,000 and not more than \$250,000 per violation,
3 and not to exceed \$1,000,000 for all such violations
4 adjudicated in a single proceeding.”;

5 (3) in paragraph (2)(C), by striking “paragraph
6 (3)(A)” and inserting “paragraph (4)(A)”;

7 (4) in paragraph (4), as so redesignated, by
8 striking “paragraph (1) or (2)” each place it ap-
9 pears and inserting “paragraph (1), (2), or (3)”;
10 and

11 (5) in paragraph (6), as so redesignated, by
12 striking “paragraph (4)” each place it appears and
13 inserting “paragraph (5)”.

14 **SEC. 103. CONFORMING AMENDMENTS.**

15 (a) REGULATION OF BIOLOGICAL PRODUCTS.—Sec-
16 tion 351(j) of the Public Health Service Act (42 U.S.C.
17 262(j)) is amended by inserting “, including the require-
18 ments under section 505(o) of such Act,” after “, and Cos-
19 metic Act”.

20 (b) CONTENT OF A NEW DRUG APPLICATION.—Sec-
21 tion 505(b)(1) of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 355(b)) is amended—

23 (1) in subparagraph (F), by striking “and”;
24 and

1 (2) in subparagraph (G), by striking the period
2 and inserting the following: “, and (H) a proposed
3 risk evaluation and mitigation strategy as described
4 under subsection (o).”.

5 (c) WITHDRAWAL OR SUSPENSION OF APPROVAL.—
6 Section 505(e) of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 355(e)) is amended by adding at the end
8 the following: “The Secretary may withdraw the approval
9 of an application submitted under subsection (b) or (j),
10 or suspend the approval of such an application, as pro-
11 vided under this subsection, without first ordering the ap-
12 plicant to submit an assessment of the approved risk eval-
13 uation and mitigation strategy for the drug under sub-
14 section (o)(5)(B)(V).”.

15 (d) DRUGS SUBJECT TO AN ABBREVIATED NEW
16 DRUG APPLICATION.—Section 505(j)(2) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is
18 amended by adding at the end the following:

19 “(D) RISK EVALUATION AND MITIGATION STRATEGY
20 REQUIREMENT.—A drug that is the subject of an abbre-
21 viated new drug application under this subsection shall be
22 subject to each element of the risk evaluation and mitiga-
23 tion strategy required under subsection (o) for the applica-
24 ble listed drug, except for any post-approval clinical trial

1 requirement described under paragraph (3)(F) of such
2 subsection.”.

3 (e) NO EFFECT ON MANUFACTURING CHANGES
4 THAT DO NOT REQUIRE PREAPPROVAL.—Subsection (d)
5 of section 506A (21 U.S.C. 356a) of the Federal Food,
6 Drug, and Cosmetic Act is amended by adding at the end
7 the following:

8 “(4) ASSESSMENT OF RISK EVALUATION AND
9 MITIGATION STRATEGY.—In the case of a manufac-
10 turing change to which this subsection applies for
11 which the submission of a supplemental application
12 is not required under paragraph (1)(A) or for which
13 distribution of the drug involved may commence
14 upon the receipt by the Secretary of a supplemental
15 application for the change under paragraph
16 (3)(B)(ii), the submission of an assessment of the
17 approved risk evaluation and mitigation strategy for
18 the drug under subsection (o)(5)(B) is not re-
19 quired.”.

20 (f) USER FEES.—Subparagraph (F) of section
21 735(6) of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 379g(6)) is amended to read as follows:

23 “(F) Reviewing risk evaluation and mitiga-
24 tion strategies, and collecting, developing, and
25 reviewing safety information on drugs, includ-

1 ing adverse event reports, and conducting post-
2 approval studies.”.

3 **SEC. 104. DRUG LABELING.**

4 (a) DATABASE OF DRUG LABELING.—Not later than
5 the effective date of this title, the Secretary of Health and
6 Human Services (referred to in this Act as the “Sec-
7 retary”), through the Commissioner of Food and Drugs,
8 shall establish a searchable database accessible through a
9 link on the homepage of the Internet website of the Food
10 and Drug Administration through which the Secretary
11 shall make accessible to the public the approved profes-
12 sional labeling and any required patient labeling of each
13 drug approved under section 505 of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under
15 section 351 of the Public Health Service Act (42 U.S.C.
16 262).

17 (b) POSTING UPON APPROVAL.—The Secretary,
18 through the Commissioner of Food and Drugs, shall post
19 the approved professional labeling and any required pa-
20 tient labeling of a drug approved under such section 505
21 or licensed under such section 351 not later than 5 days
22 after the date the drug is approved, including in a supple-
23 mental application with respect to a labeling change.

24 (c) POSTING WITH RESPECT TO DRUGS APPROVED
25 BEFORE EFFECTIVE DATE.—Not later than 12 months

1 after the effective date of this title, the Secretary shall
2 post the approved professional labeling and any required
3 patient labeling for a drug approved under such section
4 505 or licensed under such section 351 before the effective
5 date of this title. In carrying out the preceding sentence,
6 the Secretary shall give priority to—

7 (1) drugs for which a Medication Guide, as pro-
8 vided for under part 208 of title 21, Code of Federal
9 Regulations (or any successor regulations), is re-
10 quired;

11 (2) drugs deemed to have a risk evaluation and
12 mitigation strategy under subsection (c) of section
13 105; and

14 (3) drugs that are most widely prescribed for
15 use by patients.

16 (d) MEDICATION GUIDES.—Not later than the effec-
17 tive date of this title, the Secretary, through the Commis-
18 sioner of Food and Drugs, shall establish on the Internet
19 website page for the database required under subsection
20 (a) a link to a list of each drug, whether approved under
21 such section 505 or licensed under such section 351, for
22 which a Medication Guide, as provided for under part 208
23 of title 21, Code of Federal Regulations (or any successor
24 regulations), is required.

1 **SEC. 105. EFFECTIVE DATE AND APPLICABILITY.**

2 (a) EFFECTIVE DATE.—This title shall take effect 90
3 days after the date of enactment of this Act.

4 (b) DRUGS DEEMED TO HAVE RISK EVALUATION
5 AND MITIGATION STRATEGIES.—

6 (1) IN GENERAL.—The following drugs ap-
7 proved before the effective date of this title shall be
8 deemed to have an approved risk evaluation and
9 mitigation strategy under such section 505(o):

10 (A) A drug for which there are in effect on
11 the effective date of this title restrictions on
12 distribution and use required under subpart H
13 of part 314, title 21 of the Code of Federal
14 Regulations, or otherwise agreed to by the ap-
15 plicant and the Secretary for such drug.

16 (B) A drug approved after October 1,
17 2002, under a human drug application or sup-
18 plement (as defined in section 735 of the Fed-
19 eral Food, Drug, and Cosmetic Act (21 U.S.C.
20 379g), for which there is in effect, on the effec-
21 tive date of this title—

22 (i) a black box warning; or

23 (ii) a Medication Guide as provided
24 for under part 208 of title 21, Code of
25 Federal Regulations (or any successor reg-
26 ulations).

1 (2) RISK EVALUATION AND MITIGATION STRAT-
2 EGY.—The approved risk evaluation and mitigation
3 strategy deemed in effect for a drug under para-
4 graph (1) shall consist of the elements described in
5 subparagraphs (A) and (B) of paragraph (2) of such
6 section 505(o) and the black box warning, Medica-
7 tion Guide, or restrictions on distribution and use in
8 effect for such drug on the effective date of this
9 title.

10 (3) NOTIFICATION.—Not later than the effec-
11 tive date of this title, the Secretary shall notify the
12 applicant for each drug described in paragraph
13 (1)—

14 (A) that such drug is deemed to have an
15 approved risk evaluation and mitigation strat-
16 egy pursuant to such paragraph; and

17 (B) of the date, which shall be no sooner
18 than 6 months after the applicant is so notified,
19 by which the applicant shall submit to the Sec-
20 retary an assessment of such approved strategy
21 under paragraph (5)(B) of such section 505(o).

22 (4) ENFORCEMENT ONLY AFTER ASSESSMENT
23 AND REVIEW.—Neither the Secretary nor the Attor-
24 ney General may seek to enforce a requirement of a
25 risk evaluation and mitigation strategy deemed in ef-

1 fect under paragraph (1) before the Secretary has
2 completed review of, and acted on, the first assess-
3 ment of such strategy under such section 505(o).

4 (c) OTHER DRUGS APPROVED BEFORE THE EFFEC-
5 TIVE DATE.—The Secretary, on a case-by-case basis, may
6 require the applicant for a drug approved before the effec-
7 tive date of this title to which subsection (b) does not
8 apply to submit an assessment and proposed risk evalua-
9 tion and mitigation strategy as provided for in paragraph
10 (5)(B) of such section 505(o) if the Secretary determines
11 that there is information with respect to such drug that
12 indicates that—

13 (1) an element described under paragraph
14 (2)(A) of such section 505(o) may require modifica-
15 tion; or

16 (2) a standard for adding an element described
17 in paragraph (3) or (4) that is not in effect with re-
18 spect to such drug may apply to such drug.

19 **SEC. 106. STRATEGIC PLAN ON INFORMATION TECH-**
20 **NOLOGY.**

21 Not later than 180 days after the date of enactment
22 of this title, the Secretary shall submit to the Committee
23 on Health, Education, Labor, and Pensions and the Com-
24 mittee on Appropriations of the Senate and the Committee
25 on Energy and Commerce and the Committee on Appro-

1 priations of the House of Representatives, a strategic plan
2 on information technology that includes—

3 (1) an assessment of the information technology
4 needed by the Food and Drug Administration to
5 comply with the requirements of this title (and the
6 amendments made by this title);

7 (2) an assessment of the extent to which the
8 current information technology assets of the Food
9 and Drug Administration are sufficient to meet the
10 needs assessment under paragraph (1);

11 (3) a plan for enhancing the information tech-
12 nology assets of the Food and Drug Administration
13 toward meeting the needs assessment under para-
14 graph (1); and

15 (4) an assessment of additional resources need-
16 ed to so enhance the information technology assets
17 of the Food and Drug Administration.

18 **TITLE II—REAGAN-UDALL INSTI-**
19 **TUTE FOR APPLIED BIO-**
20 **MEDICAL RESEARCH**

21 **SEC. 201. THE REAGAN-UDALL INSTITUTE FOR APPLIED**
22 **BIOMEDICAL RESEARCH.**

23 (a) IN GENERAL.—Chapter VII of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-
25 ed by adding at the end the following:

1 **“Subchapter H—Establishment of Reagan-**
2 **Udall Institute for Applied Biomedical**
3 **Research**

4 **“SEC. 360. ESTABLISHMENT AND FUNCTIONS OF THE INSTI-**
5 **TUTE.**

6 “(a) IN GENERAL.—There is established within the
7 Food and Drug Administration an Institute to be known
8 as the Reagan-Udall Institute for Applied Biomedical Re-
9 search (referred to in this subchapter as the ‘Institute’).
10 The Institute shall be headed by an Executive Director,
11 appointed by the members of the Board of Directors under
12 subsection (e).

13 “(b) PURPOSE OF INSTITUTE.—The purpose of the
14 Institute is to advance the Critical Path Initiative of the
15 Food and Drug Administration to modernize medical
16 product development and enhance product safety by—

17 “(1) initiating, sponsoring, and organizing col-
18 laborative and multidisciplinary research in the
19 sciences of developing, manufacturing, and evalu-
20 ating the safety and effectiveness of diagnostics, de-
21 vices, and drugs;

22 “(2) ensuring the broad participation of aca-
23 demic, government, and industrial researchers in the
24 work of the Institute; and

1 “(3) ensuring the maximum distribution and
2 utilization of the outcomes of such research, includ-
3 ing through publication of research results and dis-
4 semination of intellectual property generated by the
5 Institute.

6 “(c) DUTIES OF THE INSTITUTE.—The Institute
7 shall—

8 “(1) establish goals and priorities relating to
9 the sciences of developing, manufacturing, and eval-
10 uating the safety and effectiveness of diagnostics,
11 devices, and drugs;

12 “(2) identify unmet needs in the sciences of de-
13 veloping, manufacturing, and evaluating the safety
14 and effectiveness of diagnostics, devices, and drugs;

15 “(3) assess existing and proposed Federal re-
16 search and development programs relating to such
17 sciences, facilitate and encourage interagency coordi-
18 nation of such programs, and expand such programs
19 relating to such sciences, including—

20 “(A) the identification and validation of
21 biomarkers for use in diagnostic, device, and
22 drug development;

23 “(B) the development and validation of
24 animal models for human disease;

1 “(C) pharmacogenomics and inter-indi-
2 vidual variability in drug response;

3 “(D) the development of data analysis
4 technology for use in drug and device develop-
5 ment;

6 “(E) clinical trial design;

7 “(F) toxicological quality assessment tech-
8 nologies; and

9 “(G) other related matters consistent with
10 the purposes of the Institute, as determined
11 necessary by the Board;

12 “(4) award grants to, or enter into contracts or
13 cooperative agreements with, scientists and entities
14 to advance the purposes of the Institute pursuant to
15 the processes established in the by-laws under sub-
16 section (d)(2)(A);

17 “(5) release and publish information and data
18 and, to the extent practicable, license, distribute,
19 and release material, reagents, and techniques to
20 maximize, promote, and coordinate the availability of
21 such material, reagents, and techniques for use by
22 the Food and Drug Administration, corporate spon-
23 sors, nonprofit organizations, and academic and in-
24 dustrial researchers;

25 “(6) ensure that—

1 “(A) action is taken as necessary to obtain
2 patents for inventions developed by the Insti-
3 tute or with funds from the Institute;

4 “(B) action is taken as necessary to enable
5 the licensing of inventions developed by the In-
6 stitute or with funds from the Institute; and

7 “(C) executed licenses, memoranda of un-
8 derstanding, material transfer agreements, con-
9 tracts, and other such instruments promote, to
10 the maximum extent practicable, the broadest
11 transfer and conversion to commercial and non-
12 commercial applications of licensed and pat-
13 ented inventions of the Institute consistent with
14 subsection (b)(3);

15 “(7) recruit scientists and hold or sponsor (in
16 whole or in part) meetings as appropriate to further
17 the purposes of the Institute;

18 “(8) provide objective clinical and scientific in-
19 formation to the Food and Drug Administration
20 and, upon request, to other Federal agencies;

21 “(9) conduct annual audits of research activi-
22 ties that are supported by the Institute; and

23 “(10) carry out such other activities consistent
24 with the purposes of the Institute as the Board de-
25 termines appropriate.

1 “(d) BOARD OF DIRECTORS.—

2 “(1) ESTABLISHMENT.—

3 “(A) IN GENERAL.—The Institute shall
4 have a Board of Directors (referred to in this
5 subchapter as the ‘Board’), which shall be com-
6 posed of ex officio and appointed members in
7 accordance with this subsection. All appointed
8 members of the Board shall be voting members.

9 “(B) EX OFFICIO MEMBERS.—The ex offi-
10 cio members of the Board shall be—

11 “(i) the immediate past Chair of
12 Board of Directors of the Institute;

13 “(ii) the Commissioner of Food and
14 Drugs; and

15 “(iii) the Director of the National In-
16 stitutes of Health.

17 “(C) APPOINTED MEMBERS.—

18 “(i) IN GENERAL.—The ex officio
19 members of the Board under subparagraph
20 (B) shall, by majority vote, appoint to the
21 Board 12 individuals. Of such appointed
22 members—

23 “(I) 3 shall be representatives of
24 the general pharmaceutical, device,
25 and biotechnology industries;

1 “(II) 1 shall be a representative
2 of the general biomedical research
3 field;

4 “(III) 3 shall be representatives
5 of the Food and Drug Administration;

6 “(IV) 2 shall be representatives
7 of the National Institutes of Health;

8 “(V) 1 shall be a representative
9 of the Institute of Medicine;

10 “(VI) 1 shall be a representative
11 of academic research organizations;
12 and

13 “(VII) 1 shall be a representative
14 of patient advocacy organizations.

15 “(ii) REQUIREMENT.—Not less
16 than—

17 “(I) 3 of the individuals de-
18 scribed under clause (i) shall have a
19 background in clinical pharmacology;
20 and

21 “(II) 2 of such individuals shall
22 have a background in medical device
23 engineering or in biomedical engineer-
24 ing.

25 “(2) DUTIES OF BOARD.—The Board shall—

1 “(A) establish by-laws for the Institute
2 that—

3 “(i) are published in the Federal Reg-
4 ister and available for public comment;

5 “(ii) establish licensing, distribution,
6 and publication policies that support the
7 widest and least restrictive use by the pub-
8 lic of information and inventions developed
9 by the Institute or with Institute funds to
10 carry out the duties described in para-
11 graphs (5) and (6) of subsection (c);

12 “(iii) specify criteria and processes for
13 the review of proposals and awarding of
14 grants and contracts that include peer re-
15 view and that are substantially consistent
16 with those established by other government
17 organizations, such as the National Insti-
18 tutes of Health and the National Science
19 Foundation;

20 “(iv) specify a process for annual
21 Board review of the operations of the Insti-
22 tute; and

23 “(v) establish specific duties of the
24 Executive Director;

1 “(B) identify and prioritize the scientific
2 needs that may be effectively and uniquely ad-
3 dressed by the Institute;

4 “(C) prioritize and provide overall direction
5 to the research activities of the Institute;

6 “(D) evaluate the performance of the Ex-
7 ecutive Director; and

8 “(E) carry out any other necessary activi-
9 ties regarding the functioning of the Institute.

10 “(3) ADDITIONAL BOARD FUNCTIONS.—

11 “(A) IN GENERAL.—The Board may estab-
12 lish 1 or more Critical Path Institutes to con-
13 duct multidisciplinary and collaborative re-
14 search, education, and outreach, and to mod-
15 ernize the sciences of developing, manufac-
16 turing, and evaluating the safety and effective-
17 ness of diagnostics, devices, and drugs.

18 “(B) ELIGIBILITY.—To be eligible to host
19 a Critical Path Institute described in subpara-
20 graph (A), an entity shall—

21 “(i) be a State or local government,
22 institution of higher education, or non-
23 profit entity with demonstrated ability,
24 personnel, and clinical and other technical
25 expertise to undertake the duties con-

1 sistent with the activities in subparagraph
2 (A); and

3 “(ii) submit to the Board an applica-
4 tion at such time, in such manner, and
5 containing such information as the Board
6 may require.

7 “(4) CHAIR.—The ex officio members of the
8 Board under paragraph (1)(B) shall designate an
9 appointed member of the Board to serve as the
10 Chair of the Board.

11 “(5) TERMS AND VACANCIES.—

12 “(A) TERM.—The term of office of each
13 member of the Board appointed under para-
14 graph (1)(C) shall be 4 years, except that the
15 terms of offices for the initial appointed mem-
16 bers of the Board shall expire on a staggered
17 basis as determined by the ex officio members.

18 “(B) VACANCY.—Any vacancy in the mem-
19 bership of the Board—

20 “(i) shall not affect the power of the
21 remaining members to execute the duties
22 of the Board; and

23 “(ii) shall be filled by appointment by
24 the ex officio members of the Board in the

1 manner described under paragraph
2 (1)(C)(i).

3 “(C) PARTIAL TERM.—If a member of the
4 Board does not serve the full term applicable
5 under subparagraph (A), the individual ap-
6 pointed by the ex officio members of the Board
7 in the manner described under paragraph
8 (1)(C)(i) to fill the resulting vacancy shall be
9 appointed for the remainder of the term of the
10 predecessor of the individual.

11 “(D) SERVING PAST TERM.—A member of
12 the Board may continue to serve after the expi-
13 ration of the term of the member until a suc-
14 cessor is appointed.

15 “(6) COMPENSATION.—Members of the Board
16 may not receive compensation for service on the
17 Board. Such members may be reimbursed for travel,
18 subsistence, and other necessary expenses incurred
19 in carrying out the duties of the Board, as set forth
20 in the bylaws issued by the Board.

21 “(e) EXECUTIVE DIRECTOR.—

22 “(1) IN GENERAL.—The Board shall appoint an
23 Executive Director who shall serve at the pleasure of
24 the Board. The Executive Director shall be respon-
25 sible for the day-to-day operations of the Institute

1 and shall have such specific duties and responsibil-
2 ities as the Board shall prescribe.

3 “(2) COMPENSATION.—The compensation of
4 the Executive Director shall be fixed by the Board
5 but shall not be greater than the compensation of
6 the Commissioner of Food and Drugs.

7 “(f) ADMINISTRATIVE POWERS.—In carrying out this
8 subchapter, the Board, acting through the Executive Di-
9 rector, may—

10 “(1) hire 1 or more officers, employees, and
11 agents, as may be necessary, and define their duties;

12 “(2) hire, promote, compensate, and discharge
13 officers and employees of the Institute;

14 “(3) prescribe the manner in which—

15 “(A) officers, employees, and agents of the
16 Institute are selected;

17 “(B) real or personal property of the Insti-
18 tute is acquired, held, and transferred;

19 “(C) general operations of the Institute are
20 to be conducted; and

21 “(D) the privileges granted to the Board
22 by law are exercised and enjoyed;

23 “(4) with the consent of the applicable executive
24 department or independent agency, use the informa-

1 tion, services, and facilities of such department or
2 agencies in carrying out this section;

3 “(5) enter into contracts with public and pri-
4 vate organizations for the writing, editing, printing,
5 and publishing of books and other material;

6 “(6) hold, administer, invest, and spend any
7 gift, devise, or bequest of real or personal property
8 made to the Institute under subsection (g);

9 “(7) enter into such other contracts, leases, co-
10 operative agreements, and other transactions as the
11 Executive Director considers appropriate to conduct
12 the activities of the Institute;

13 “(8) appoint other groups of advisors as may be
14 determined necessary to carry out the functions of
15 the Institute; and

16 “(9) exercise other powers as set forth in this
17 section, and such other incidental powers as are nec-
18 essary to carry out its powers, duties, and functions
19 in accordance with this subchapter.

20 “(g) ACCEPTANCE OF FUNDS FROM OTHER
21 SOURCES.—The Executive Director may accept on behalf
22 of the Institute, any funds, gifts, devises, or bequests of
23 real or personal property made to the Institute from
24 sources outside the Food and Drug Administration, in-

1 cluding private entities, for the purposes of carrying out
2 the duties of the Institute.

3 “(h) ANNUAL REPORTS.—

4 “(1) REPORTS TO INSTITUTE.—Any recipient of
5 a grant, contract, or cooperative agreement from the
6 Institute under this section shall submit to the Insti-
7 tute a report on an annual basis that describes the
8 activities carried out under such grant, contract, or
9 cooperative agreement.

10 “(2) REPORT TO CONGRESS.—Beginning with
11 fiscal year 2008, the Executive Director shall submit
12 to the Committee on Health, Education, Labor, and
13 Pensions of the Senate and the Committee on En-
14 ergy and Commerce of the House of Representatives
15 an annual report that—

16 “(A) describes the activities of the Insti-
17 tute and of the recipients of a grant, contract,
18 or cooperative agreement under this section;

19 “(B) provides a specific accounting of the
20 source of all funds used by the Institute to
21 carry out such activities; and

22 “(C) describes how such funds were used
23 by the Institute.

24 “(i) SEPARATION OF FUNDS.—The Executive Direc-
25 tor shall ensure that the funds received from the Treasury

1 are held in separate accounts from funds received from
2 private entities under subsection (g).

3 “(j) AUTHORIZATION OF APPROPRIATIONS.—

4 “(1) ADMINISTRATIVE PROVISIONS.—

5 “(A) IN GENERAL.—There are authorized
6 to be appropriated \$20,000,000 for each of fis-
7 cal years 2008 through 2013 to carry out this
8 section, section 361, and section 362.

9 “(B) LIMITATION.—From amounts appro-
10 priated for a fiscal year under subparagraph
11 (A), the Secretary shall use not less than
12 \$1,200,000 to carry out subsections (a), (b),
13 and (d) through (i).

14 “(2) LIMITATION.—Beginning with fiscal year
15 2013, if the Institute fails to collect at least
16 \$20,000,000 in funds from private sources for any
17 2-year period, this subchapter shall cease to have
18 force or effect.”.

19 (b) EMPLOYEES FROM OTHER FEDERAL AGEN-
20 CIES.—Chapter VII (21 U.S.C. 380 et seq.) (as amended
21 by subsection (a)) is further amended by adding at the
22 end the following:

1 **“SEC. 361. ACCEPTING EMPLOYEES FROM OTHER FEDERAL**
2 **AGENCIES.**

3 “(a) COLLABORATION WITH OTHER AGENCIES.—To
4 carry out the purposes of the Institute, the Secretary, act-
5 ing through the Commissioner of Food and Drugs and in
6 consultation with the Executive Director of the Institute,
7 may collaborate with other Federal agencies and accept
8 the services of employees from those agencies without re-
9 imbursement to those agencies.

10 “(b) DETAIL OF GOVERNMENT EMPLOYEES.—Not
11 more than 5 Federal Government employees may be de-
12 tailed to the Institute at any time for a period not to ex-
13 ceed 6 years for each such employee, and such detail shall
14 be without civil service status or privilege. Such employees
15 shall abide by the statutory, regulatory, ethical, and proce-
16 dural standards applicable to employees of the Food and
17 Drug Administration.

18 “(c) PROCUREMENT OF TEMPORARY AND INTERMIT-
19 TENT SERVICES.—The Executive Director may procure
20 temporary and intermittent services under section 3109(b)
21 of title 5, United States Code, at rates for individuals
22 which do not exceed the daily equivalent of the annual rate
23 of basic pay prescribed for level V of the Executive Sched-
24 ule under section 5316 of such title.

25 “(d) NO ADDITIONAL LIABILITY.—Nothing in this
26 section adds to any liability that the United States may

1 have under chapter 171 of title 28, United States Code
2 (commonly known as the Federal Tort Claims Act).”.

3 (c) OTHER INSTITUTE PROVISIONS.—Chapter VII
4 (21 U.S.C. 371 et seq.) (as amended by subsection (b))
5 is further amended by adding at the end the following:
6 **“SEC. 362. LOCATION OF INSTITUTE.**

7 “(a) IN GENERAL.—The Institute shall, if prac-
8 ticable, be located not more than 20 miles from the Dis-
9 trict of Columbia.

10 “(b) USE OF SPACE.—The Secretary shall consult
11 with the Administrator of General Services to ensure the
12 most cost-efficient arrangement for the leasing or pur-
13 chase of real property for adequate facilities which, if
14 practicable, shall be located at the Food and Drug Admin-
15 istration, to meet the needs of the Institute in carrying
16 out this subchapter.”.

17 (d) RECOVERY AND RETENTION OF FEES FOR FOIA
18 REQUESTS.—Chapter VII of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 371 et seq.) (as amended by sub-
20 section (c)) is further amended by adding at the end the
21 following:

1 **“SEC. 363. RECOVERY AND RETENTION OF FEES FOR FREE-**
2 **DOM OF INFORMATION REQUESTS TO THE IN-**
3 **STITUTE.**

4 “(a) IN GENERAL.—The Secretary, acting through
5 the Commissioner of Food and Drugs, may—

6 “(1) set and charge fees, in accordance with
7 section 552(a)(4)(A) of title 5, United States Code,
8 to recover all reasonable costs incurred in processing
9 requests made under section 552 of title 5, United
10 States Code, for records obtained or created by the
11 Institute under this Act or any other Federal law for
12 which responsibility for administration has been del-
13 egated to the Institute by the Secretary;

14 “(2) retain all fees charged for such requests;
15 and

16 “(3) establish an accounting system and proce-
17 dures to control receipts and expenditures of fees re-
18 ceived under this section.

19 “(b) USE OF FEES.—The Secretary and the Commis-
20 sioner of Food and Drugs shall not use fees received under
21 this section for any purpose other than funding the proc-
22 essing of requests described in subsection (a)(1). Such fees
23 shall not be used to reduce the amount of funds made
24 available to carry out other provisions of this Act.

25 “(c) WAIVER OF FEES.—Nothing in this section shall
26 supersede the right of a requester to obtain a waiver of

1 fees pursuant to section 552(a)(4)(A) of title 5, United
2 States Code.”.

3 **TITLE III—CLINICAL TRIALS**

4 **SEC. 301. CLINICAL TRIAL REGISTRY DATABASE AND CLIN-** 5 **ICAL TRIAL RESULTS DATABASE.**

6 (a) IN GENERAL.—Section 402(j) of the Public
7 Health Service Act (42 U.S.C. 282(j)) is amended to read
8 as follows:

9 “(j) CLINICAL TRIAL REGISTRY DATABASE; CLIN-
10 ICAL TRIAL RESULTS DATABASE.—

11 “(1) DEFINITIONS; REQUIREMENT.—

12 “(A) DEFINITIONS.—In this subsection:

13 “(i) CLINICAL TRIAL INFORMATION.—

14 The term ‘clinical trial information’ means
15 those data elements that are necessary to
16 complete an entry in the clinical trial reg-
17 istry database under paragraph (2) or the
18 clinical trial results database under para-
19 graph (3), as applicable.

20 “(ii) COMPLETION DATE.—The term
21 ‘completion date’ means, with respect to a
22 clinical trial, the date on which the clinical
23 trial concluded, was abandoned, or was
24 suspended.

1 “(iii) DRUG.—The term ‘drug’ means
2 a drug as defined in section 201(g) of the
3 Federal Food, Drug, and Cosmetic Act or
4 a biological product as defined in section
5 351 of this Act.

6 “(iv) RESPONSIBLE PARTY.—The
7 term ‘responsible party’, with respect to a
8 clinical trial of a drug, means the sponsor
9 of the clinical trial or the principal investi-
10 gator of such clinical trial if so designated
11 by such sponsor.

12 “(B) REQUIREMENT.—The Secretary shall
13 develop a mechanism by which—

14 “(i) the responsible party for each ap-
15 plicable clinical trial shall submit the iden-
16 tity and contact information of such re-
17 sponsible party to the Secretary at the
18 time of submission of clinical trial informa-
19 tion under paragraph (2); and

20 “(ii) other Federal agencies may iden-
21 tify the responsible party for an applicable
22 clinical trial.

23 “(2) CLINICAL TRIAL REGISTRY DATABASE.—

1 “(A) APPLICABLE CLINICAL TRIAL.—For
2 purposes of this paragraph the term ‘applicable
3 clinical trial’—

4 “(i) means—

5 “(I) a clinical trial completed be-
6 fore the drug is approved under sec-
7 tion 505 of the Federal Food, Drug,
8 and Cosmetic Act or licensed under
9 section 351 of this Act that is—

10 “(aa) a therapeutic or
11 chemopreventive exploratory trial
12 to verify the efficacy and estab-
13 lish appropriate doses for the
14 drug; or

15 “(bb) a therapeutic or
16 chemopreventive confirmatory
17 trial; or

18 “(II) a clinical trial completed
19 after the drug is approved under such
20 section 505 or licensed under such
21 section 351.

22 “(ii) EXCEPTION.—A clinical trial
23 under clause (i)(I) does not include an ex-
24 ploratory trial that is intended solely to as-

1 sess safety or solely to evaluate pharmaco-
2 kinetics.

3 “(B) ESTABLISHMENT.—To enhance pa-
4 tient enrollment and provide a mechanism to
5 track subsequent progress of clinical trials, the
6 Secretary, acting through the Director of NIH,
7 shall establish and administer a clinical trial
8 registry database in accordance with this sub-
9 section (referred to in this subsection as the
10 ‘registry database’). The Director of NIH shall
11 ensure that the registry database is made pub-
12 licly available through the Internet.

13 “(C) SEARCHABLE CATEGORIES.—The Di-
14 rector of NIH shall ensure that the public may
15 search the entries in the registry database by—

16 “(i)(I) the indication being studied in
17 the clinical trial, using Medical Subject
18 Headers (MeSH) descriptors; or

19 “(II) the safety issue being studied in
20 the clinical trial;

21 “(ii) the phase of the clinical trial;

22 “(iii) whether enrollment status of the
23 clinical trial is open or closed; and

24 “(iv) within the document described in
25 subparagraph (D)(ii)(II)—

1 “(I) the sponsor of the clinical
2 trial;

3 “(II) each financial sponsor of
4 the clinical trial; and

5 “(III) the principal investigator
6 of the clinical trial.

7 “(D) CONTENTS.—

8 “(i) IN GENERAL.—The responsible
9 party for an applicable clinical trial shall
10 submit to the Director of NIH for inclu-
11 sion in the registry database the clinical
12 trial information described in clause (ii).

13 “(ii) PUBLICLY AVAILABLE ELE-
14 MENTS.—In submitting clinical trial infor-
15 mation to the Director of NIH for inclu-
16 sion in the registry database, the respon-
17 sible party shall include, with respect to
18 such clinical trial, the following informa-
19 tion:

20 “(I) The information described
21 under clauses (i) through (iii) of sub-
22 paragraph (C).

23 “(II) A non-promotional sum-
24 mary document that includes the fol-
25 lowing information:

1 “(aa) The purpose of the
2 clinical trial outlined in a para-
3 graph.

4 “(bb) If the drug is cur-
5 rently approved, the pharma-
6 cological class description.

7 “(cc) The sponsor of the
8 clinical trial.

9 “(dd) Each financial sponsor
10 of the clinical trial.

11 “(ee) The principal investi-
12 gator of the clinical trial.

13 “(ff) Each location of the
14 clinical trial.

15 “(gg) Contact information
16 for each location of the clinical
17 trial.

18 “(hh) The inclusion and ex-
19 clusion criteria of the clinical
20 trial.

21 “(ii) The target number of
22 subjects to be enrolled in the
23 clinical trial.

24 “(jj) The expected duration
25 of the clinical trial.

1 “(kk) If the drug is not ap-
2 proved under section 505 of the
3 Federal Food, Drug, and Cos-
4 metic Act or licensed under sec-
5 tion 351 of this Act, whether or
6 not there is an opportunity to ac-
7 cess the drug outside of the clin-
8 ical trial for those who do not
9 qualify for enrollment in the trial
10 and how to obtain information
11 about such an opportunity.

12 “(E) TRUTHFUL CLINICAL TRIAL INFOR-
13 MATION.—The clinical trial information sub-
14 mitted by a responsible party under this para-
15 graph shall not be false or misleading in any
16 particular.

17 “(F) RESTRICTED ELEMENTS.—

18 “(i) IN GENERAL.—The responsible
19 party for an applicable clinical trial shall
20 submit to the Director of NIH for inclu-
21 sion in the registry database the clinical
22 trial information described in clause (ii).
23 The Director of NIH shall ensure that the
24 information submitted under this subpara-
25 graph is not made publicly available.

1 “(ii) RESTRICTED INFORMATION.—

2 The responsible party shall submit—

3 “(I) on the date that clinical trial
4 information is first submitted to the
5 Director of NIH—

6 “(aa) the proposed length of
7 the data analysis period after
8 conclusion of the clinical trial;
9 and

10 “(bb) the target completion
11 date of the trial; and

12 “(II) not later than 30 days after
13 the target completion date proposed in
14 subclause (I)(bb), a statement that
15 the clinical trial is complete, or a
16 progress report that includes a revised
17 target completion date for the clinical
18 trial and the reason for the delay.

19 “(iii) REVISION OF DATE FOR SUBMIS-
20 SION.—The responsible party for an appli-
21 cable clinical trial shall have one oppor-
22 tunity to revise the target completion date
23 under clause (ii)(II).

24 “(iv) ENROLLMENT.—The responsible
25 party for an applicable clinical trial shall

1 update the enrollment status submitted
2 under subparagraph (C)(iii) not later than
3 30 days after the enrollment status of such
4 trial closes.

5 “(v) DURATION.—The responsible
6 party for an applicable clinical trial shall
7 update the expected duration of a clinical
8 trial submitted under subparagraph
9 (D)(ii)(II)(jj) if the expected duration of
10 the clinical trial changes by more than 25
11 percent.

“(G) TIMING OF SUBMISSION.—The clinical trial information for an applicable clinical trial required to be submitted under this paragraph shall be submitted after such clinical trial is approved by the applicable institutional review boards and before the first patient is enrolled in such clinical trial.

19 “(3) CLINICAL TRIALS RESULTS DATABASE.—

“(A) APPLICABLE CLINICAL TRIAL.—For
purposes of this paragraph, the term ‘applicable
clinical trial’ means—

23 “(i) a clinical trial completed before
24 the drug is approved under section 505 of
25 the Federal Food, Drug, and Cosmetic Act

1 or licensed under section 351 of this Act
2 that is—

3 “(I) a therapeutic or
4 chemopreventive confirmatory trial;

5 “(II) a clinical trial for a drug
6 approved as a fast-track product
7 under section 506 of the Federal
8 Food, Drug, and Cosmetic Act, if
9 such clinical trial is used to form the
10 primary basis of an efficacy claim for
11 such drug; or

12 “(III) if required by the Sec-
13 retary under subparagraph (G)(i), a
14 clinical trial described in paragraph
15 (2)(A)(i)(I)(aa); or

16 “(ii) a clinical trial completed after
17 the drug is approved under such section
18 505 or licensed under such section 351.

19 “(B) ESTABLISHMENT.—To ensure that
20 results of clinical trials are made public and
21 that patients and providers have current infor-
22 mation regarding the results of clinical trials,
23 the Secretary, acting through the Director of
24 NIH, shall establish and administer a clinical
25 trial results database in accordance with this

1 subsection (referred to in this subsection as the
2 ‘results database’).

3 “(C) SEARCHABLE CATEGORIES.—The Di-
4 rector of NIH shall ensure that the public may
5 search the entries in the results database by—

6 “(i)(I) the indication studied in the
7 clinical trial, using Medical Subject Head-
8 ers (MeSH) descriptors; or

9 “(II) the safety issue studied in the
10 clinical trial;

11 “(ii) whether an application for the
12 tested indication is approved, pending ap-
13 proval, withdrawn, or not submitted;

14 “(iii) the phase of the clinical trial;

15 “(iv) the name of the drug that is the
16 subject of the clinical trial; and

17 “(v) within the documents described
18 in subclauses (II) and (III) of subpara-
19 graph (D)(ii)—

20 “(I) the sponsor of the clinical
21 trial;

22 “(II) each financial sponsor of
23 the clinical trial; and

24 “(III) the principal investigator
25 of the clinical trial.

1 “(D) CONTENTS.—

2 “(i) IN GENERAL.—The responsible
3 party for an applicable clinical trial shall
4 submit to the Director of NIH for inclu-
5 sion in the results database the clinical
6 trial information described in clause (ii).

7 “(ii) REQUIRED ELEMENTS.—In sub-
8 mitting clinical trial information for an ap-
9 plicable clinical trial to the Director of
10 NIH for inclusion in the results database,
11 the responsible party shall include, with re-
12 spect to such clinical trial, the following in-
13 formation:

14 “(I) The information described in
15 clauses (i) through (iv) of subpara-
16 graph (C).

17 “(II) A non-promotional sum-
18 mary document that is written in non-
19 technical, understandable language for
20 patients that includes the following:

21 “(aa) The purpose of the
22 clinical trial.

23 “(bb) The sponsor of the
24 clinical trial.

1 “(cc) Each financial sponsor
2 of the clinical trial.

3 “(dd) The principal investi-
4 gator of the clinical trial.

5 “(ee) Contact information
6 for the principal investigator of
7 the clinical trial.

8 “(ff) A description of pa-
9 tient population tested in the
10 clinical trial.

11 “(gg) A general description
12 of the clinical trial and results,
13 including—

14 “(AA) a description of
15 and the reasons for any
16 changes in the clinical trial
17 design that occurred since
18 the date of submission of
19 clinical trial information for
20 inclusion in the registry
21 database established under
22 paragraph (2); and

23 “(BB) a description of
24 any significant safety infor-
25 mation.

1 “(III) A non-promotional sum-
2 mary document that is technical in
3 nature that includes the following:

4 “(aa) The purpose of the
5 clinical trial.

6 “(bb) The sponsor of the
7 clinical trial.

8 “(cc) Each financial sponsor
9 of the clinical trial.

10 “(dd) The principal investi-
11 gator of the clinical trial.

12 “(ee) Contact information
13 for the principal investigator of
14 the clinical trial.

15 “(ff) A description of the
16 patient population tested in the
17 clinical trial.

18 “(gg) A general description
19 of the clinical trial and results,
20 including a description of and the
21 reasons for any changes in the
22 clinical trial design that occurred
23 since the date of submission of
24 clinical trial information for the
25 clinical trial in the registry data-

1 base established under paragraph
2 (2).

3 “(hh) Summary data de-
4 scribing the results, including the
5 following:

6 “(AA) Whether the pri-
7 mary endpoint was achieved,
8 including relevant statistics.

9 “(BB) An assessment
10 of any secondary endpoints,
11 if applicable, including rel-
12 evant statistics.

13 “(CC) Any significant
14 safety information, including
15 a summary of the incidence
16 of serious adverse events ob-
17 served in the clinical trial
18 and the most common ad-
19 verse events observed in the
20 clinical trial for which there
21 was a statistically significant
22 increase over the rate ob-
23 served for the control arm of
24 the clinical trial.

1 “(IV) Peer-reviewed publications
2 based on the results of the clinical
3 trial, if any.

4 “(V) The completion date of the
5 clinical trial.

6 “(VI) A link to the Internet web
7 posting of any adverse regulatory ac-
8 tions taken by the Food and Drug
9 Administration, such as a warning let-
10 ter, that was substantively based on
11 the clinical trial design, outcome, or
12 representation made by the applicant
13 about the design or outcome of the
14 clinical trial.

15 “(E) TIMING.—A responsible party shall
16 submit to the Director of NIH for inclusion in
17 the results database clinical trial information
18 for an applicable clinical trial not later than 30
19 days after—

20 “(i) the conclusion of the data anal-
21 ysis period described in paragraph
22 (2)(F)(ii)(I)(aa); or

23 “(ii) the target completion date of the
24 clinical trial as updated under paragraph
25 (2)(F)(iii), if applicable.

1 “(F) TRUTHFUL CLINICAL TRIAL INFOR-
2 MATION.—The clinical trial information sub-
3 mitted by a responsible party under this para-
4 graph shall not be false or misleading in any
5 particular.

6 “(G) INCLUSION OF EARLIER CLINICAL
7 TRIALS.—

8 “(i) IN GENERAL.—The Secretary
9 may, subject to clause (ii), require through
10 rulemaking the submission of clinical trial
11 information for the clinical trials described
12 in paragraph (2)(A)(i)(I)(aa) to the Direc-
13 tor of NIH for inclusion in the results
14 database.

15 “(ii) CONDITIONS FOR REQUIRING IN-
16 CLUSION OF EARLIER TRIALS.—The Sec-
17 retary may promulgate regulations pursu-
18 ant to clause (i) if—

19 “(I) the Comptroller General of
20 the United States has submitted to
21 the Secretary the report described
22 under clause (iii); and

23 “(II) such report recommends
24 the inclusion in the results database
25 of clinical trial information for the

1 clinical trials described under para-
2 graph (2)(A)(i)(I)(aa).

3 “(iii) STUDY BY GAO.—Not earlier
4 than 2 years after the results database has
5 been established, the Comptroller General
6 of the United States shall initiate a report
7 that—

8 “(I) evaluates the operation of
9 the database, including with respect to
10 cost, burden on drug sponsors and
11 agencies, and the value of inclusion in
12 the results database of clinical trial
13 information with respect to clinical
14 trials described in paragraph
15 (2)(A)(i)(I)(aa);

16 “(II) recommends whether or not
17 clinical trial information for such clin-
18 ical trials should be included in the re-
19 sults database;

20 “(III) if the recommendation
21 under subclause (II) is to include the
22 clinical trial information for such trial
23 in the results database, recommends
24 whether such information should be
25 included in the same manner as the

1 clinical trial information of other ap-
2 plicable clinical trials, or if modifica-
3 tions are necessary;

4 “(IV) provides recommendations
5 for any modifications described under
6 subclause (III);

7 “(V) is submitted to the Com-
8 mittee on Health, Education, Labor,
9 and Pensions of the Senate, the Com-
10 mittee on Energy and Commerce of
11 the House of Representatives, and the
12 Secretary.

13 “(H) CHANGE IN REGULATORY STATUS.—
14 The responsible party for an applicable clinical
15 trial shall update the regulatory status sub-
16 mitted under subparagraph (C)(ii) of a drug
17 that is the subject of an applicable clinical trial
18 within 30 days of a change in such status.

19 “(I) PUBLIC AVAILABILITY OF RESULTS.—

20 “(i) PRE-APPROVAL STUDIES.—Ex-
21 cept as provided in clause (iv), with respect
22 to an applicable clinical trial that is com-
23 pleted before the drug is initially approved
24 under section 505 of the Federal Food,
25 Drug, or Cosmetic Act or initially licensed

1 under section 351 of this Act, the Director
2 of NIH shall make publicly available on
3 the results database the clinical trial infor-
4 mation submitted for such clinical trial not
5 later than 30 days after—

6 “(I) the drug is approved under
7 such section 505 or licensed under
8 such section 351;

9 “(II) the Secretary issues a not
10 approvable letter for the drug under
11 such section 505 or such section 351;
12 or

13 “(III) the application under such
14 section 505 or such section 351 is
15 withdrawn.

16 “(ii) POST-APPROVAL STUDIES.—Ex-
17 cept as provided in clauses (iii) and (iv),
18 with respect to an applicable clinical trial
19 that is completed after the drug is initially
20 approved under such section 505 or ini-
21 tially licensed under such section 351, the
22 Director of NIH shall make publicly avail-
23 able on the results database the clinical
24 trial information submitted for such clin-

1 ical trial not later than 30 days after the
2 date of such submission.

3 “(iii) SEEKING APPROVAL OF A NEW
4 USE FOR THE DRUG.—

5 “(I) IN GENERAL.—If the manu-
6 facturer of the drug is the sponsor or
7 a financial sponsor of the applicable
8 clinical trial, and such manufacturer
9 certifies to the Director of NIH that
10 such manufacturer has filed, or will
11 file within 1 year, an application seek-
12 ing approval under such section 505
13 or licensing under such section 351
14 for the use studied in such clinical
15 trial (which use is not included in the
16 labeling of the approved drug), then
17 the Director of NIH shall make pub-
18 licly available on the results database
19 the clinical trial information sub-
20 mitted for such clinical trial on the
21 earlier of the date that is 30 days
22 after the date—

23 “(aa) the application is ap-
24 proved under such section 505 or
25 licensed such section 351;

1 “(bb) the Secretary issues a
2 not approvable letter for the ap-
3 plication under such section 505
4 or such section 351; or

5 “(cc) the application under
6 such section 505 or such section
7 351 is withdrawn.

8 “(II) LIMITATION ON CERTIFI-
9 CATION.—A manufacturer shall not
10 make a certification under subclause
11 (I) with respect to an applicable clin-
12 ical trial unless the manufacturer
13 makes such a certification with re-
14 spect to each applicable clinical trial
15 that is required to be submitted in an
16 application for approval of the use
17 studied in the clinical trial involved.

18 “(III) 2 YEAR LIMITATION.—The
19 clinical trial information subject to
20 subclause (I) shall be made publicly
21 available on the results database on
22 the date that is 2 years after the date
23 that the clinical trial information was
24 required to be submitted to the Direc-
25 tor of NIH if a regulatory action re-

1 ferred to in item (aa), (bb), or (cc) of
2 subclause (I) has not occurred by
3 such date.

4 “(iv) SEEKING PUBLICATION.—

5 “(I) IN GENERAL.—If the prin-
6 cipal investigator of the applicable
7 clinical trial is seeking publication in
8 a peer-reviewed journal of a manu-
9 script based on the results of the clin-
10 ical trial and the responsible party so
11 certifies to the Director of NIH, the
12 Director of NIH shall make publicly
13 available on the results database the
14 clinical trial information submitted for
15 such trial on the date that is 30 days
16 after the publication date of such
17 manuscript.

18 “(II) LIMITATION.—The clinical
19 trial information subject to subclause
20 (I) shall be made publicly available on
21 the results database on the date that
22 is 2 years after the date that the clin-
23 ical trial information was required to
24 be submitted to the Director of NIH
25 if the manuscript referred to in such

1 subclause has not been published by
2 such date.

“(J) VERIFICATION OF SUBMISSION PRIOR
TO PUBLIC AVAILABILITY.—In the case of clinical trial information that is submitted under this paragraph, but is not made publicly available pending either regulatory action or publication under clause (iii) or (iv) of subparagraph (I), as applicable, the Director of NIH shall respond to inquiries from other Federal agencies and peer-reviewed journals to verify whether such clinical trial information has been submitted but has not yet been made publicly available on the results database.

15 “(4) COORDINATION AND COMPLIANCE.—

16 “(A) CLINICAL TRIALS SUPPORTED BY
17 GRANTS FROM FEDERAL AGENCIES.—

18 “(i) IN GENERAL.—No Federal agen-
19 cy may release funds under a research
20 grant to a person who has not complied
21 with paragraphs (2) and (3) for any appli-
22 cable clinical trial for which such person is
23 the responsible party.

24 “(ii) GRANTS FROM CERTAIN FED-
25 ERAL AGENCIES.—If an applicable clinical

1 trial is funded in whole or in part by a
2 grant from the National Institutes of
3 Health, the Agency for Healthcare Re-
4 search and Quality, or the Department of
5 Veterans Affairs, any grant or progress re-
6 port forms required under such grant shall
7 include a certification that the responsible
8 party has made all required submissions to
9 the Director of NIH under paragraphs (2)
10 and (3).

11 “(iii) VERIFICATION BY FEDERAL
12 AGENCIES.—The heads of the agencies re-
13 ferred to in clause (ii), as applicable, shall
14 verify that the clinical trial information for
15 each applicable clinical trial for which a
16 grantee is the responsible party has been
17 submitted under paragraph (2) and (3), as
18 applicable, before releasing funding for a
19 grant to such grantee.

20 “(iv) NOTICE AND OPPORTUNITY TO
21 REMEDY.—If the head of an agency re-
22 ferred to in clause (ii), as applicable,
23 verifies that a grantee has not submitted
24 clinical trial information as described in
25 clause (iii), such agency head shall provide

1 notice to such grantee of such non-compli-
2 ance and allow such grantee 30 days to
3 correct such non-compliance and submit
4 the required clinical trial information.

5 “(v) CONSULTATION WITH OTHER
6 FEDERAL AGENCIES.—The Secretary
7 shall—

8 “(I) consult with other agencies
9 that conduct human studies in accord-
10 ance with section 46 of title 45, Code
11 of Federal Regulations, to determine
12 if any such studies are applicable clin-
13 ical trials under paragraph (2) or (3);
14 and

15 “(II) develop with such agencies
16 procedures comparable to those de-
17 scribed in clauses (ii), (iii), and (iv) to
18 ensure that clinical trial information
19 for such applicable clinical trials are
20 submitted under paragraphs (2) and
21 (3).

22 “(B) COORDINATION OF REGISTRY DATA-
23 BASE AND RESULTS DATABASE.—

24 “(i) IN GENERAL.—Each entry in the
25 registry database under paragraph (2)

1 shall include a link to the corresponding
2 entry in the results database under para-
3 graph (3).

4 “(ii) MISSING ENTRIES.—

5 “(I) IN GENERAL.—If, based on
6 a review of the entries in the registry
7 database under paragraph (2), the Di-
8 rector of NIH determines that a re-
9 sponsible party has failed to submit
10 required clinical trial information to
11 the results database under paragraph
12 (3), the Director of NIH shall inform
13 the responsible party involved of such
14 failure and permit the responsible
15 party to correct the failure within 30
16 days.

17 “(II) FAILURE TO CORRECT.—If
18 the responsible party does not correct
19 a failure to submit required clinical
20 trial information within the 30-day
21 period described under subclause (I),
22 the Director of NIH shall report such
23 non-compliance to the scientific peer
24 review committees of the Federal re-
25 search agencies and to the Office of

1 Human Research Subjects Protec-
2 tions.

3 “(III) PUBLIC NOTICE OF FAIL-
4 URE TO CORRECT.—The Director of
5 NIH shall include in the clinical trial
6 registry database entry and the clin-
7 ical trial results database entry for
8 each such clinical trial a notice of any
9 uncorrected failure to submit required
10 clinical trial information and shall
11 provide that the public may easily
12 search for such entries.

13 “(C) ACTION ON APPLICATIONS.—

14 “(i) VERIFICATION PRIOR TO FIL-
15 ING.—The Secretary, acting through the
16 Commissioner of Food and Drugs, shall
17 verify that the clinical trial information re-
18 quired under paragraphs (2) and (3) for
19 an applicable clinical trial is submitted
20 pursuant to such applicable paragraph—

21 “(I) when considering a drug for
22 an exemption under section 505(i) of
23 the Federal Food, Drug, and Cos-
24 metic Act, including as the drug pro-
25 gresses through the clinical trials de-

1 scribed under clause (i) of paragraph
2 (2)(A); and

“(II) prior to filing an application under section 505 of the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act that includes information from such clinical trial.

9 “(ii) NOTIFICATION.—If the respon-
10 sible party has not submitted such clinical
11 trial information, the Secretary shall notify
12 the applicant and the responsible party of
13 such non-compliance and require submis-
14 sion of such results within 30 days.

“(iii) REFUSAL TO FILE.—If the responsible party does not remedy such non-compliance within 30 days of receipt of notification under clause (iii), the Secretary shall refuse to file such application.

20 “(D) CONTENT REVIEW.—

“(i) IN GENERAL.—To assure that the summary documents described in paragraph (2)(D) and paragraph (3)(D) are non-promotional, and not false or misleading in any particular, the Secretary

1 shall compare such documents to the re-
2 sults data of the clinical trial for a rep-
3 resentative sample of applicable clinical
4 trials by—

5 “(I) acting through the Commis-
6 sioner of Food and Drugs to examine
7 the results data for such clinical trials
8 submitted to Secretary as part of an
9 application under section 505 of the
10 Federal Food, Drug, and Cosmetic
11 Act or under section 351 of this Act,
12 or in an annual status report on the
13 drug under such application;

14 “(II) acting through the Inspec-
15 tor General of the Department of
16 Health and Human Services and with
17 the Federal agency that funds such
18 clinical trial in whole or in part by a
19 grant to examine the results data for
20 such clinical trials; and

21 “(III) acting through inspections
22 under section 704 of the Federal
23 Food, Drug, and Cosmetic Act to ex-
24 amine results data for such clinical

1 trials not described in subclause (I) or
2 (II).

3 “(ii) NOTICE OF NON-COMPLIANCE.—

4 If the Secretary or Inspector General of
5 the Department of Health and Human
6 Services determines that the clinical trial
7 information submitted in such a summary
8 document is promotional, or false or mis-
9 leading in any particular, the Secretary
10 shall notify the responsible party and give
11 such party an opportunity to remedy such
12 non-compliance by submitting the required
13 revised clinical trial information within 30
14 days of such notification.

15 “(E) PENALTY FOR NON-COMPLIANCE.—In
16 determining whether to apply a penalty under
17 section 301(hh) of the Federal Food, Drug, and
18 Cosmetic Act, the Secretary, acting through the
19 Commissioner of Food and Drugs, shall con-
20 sider—

21 “(i) whether the responsible party
22 promptly corrects the non-compliance when
23 provided notice;

1 “(ii) whether the responsible party
2 has engaged in a pattern or practice of
3 non-compliance; and

4 “(iii) the extent to which the non-
5 compliance involved may have significantly
6 misled healthcare providers or patients
7 concerning the safety or effectiveness of
8 the drug involved.

9 “(5) LIMITATION ON DISCLOSURE OF CLINICAL
10 TRIAL INFORMATION.—Disclosure to the public of
11 clinical trial information submitted to the Director
12 of NIH under this subsection and requested under
13 section 552 of title 5, United States Code (com-
14 monly known as the Freedom of Information Act)
15 shall be made only as provided for in the databases
16 under paragraphs (2) and (3).

17 “(6) AUTHORIZATION OF APPROPRIATIONS.—
18 There are authorized to be appropriated to carry out
19 this subsection such sums as may be necessary.”.

20 (b) CONFORMING AMENDMENTS.—

21 (1) PROHIBITED ACTS.—Section 301 of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 331) is amended by adding at the end the following:

1 “(ii)(1) The failure to submit clinical trial informa-
2 tion as required by section 402(j) of the Public Health
3 Service Act.

4 “(2) The submission of clinical trial information
5 under section 402(j) of the Public Health Service Act that
6 is promotional or false or misleading in any particular.”.

7 (2) NEW DRUGS.—

8 (A) INVESTIGATIONAL NEW DRUGS.—Sec-
9 tion 505(i) of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 355(i)) is amended—

11 (i) in paragraph (1)—

12 (I) in subparagraph (C), by strik-
13 ing “and” after the semicolon;

14 (II) in subparagraph (D), by
15 striking the period at the end and in-
16 serting “; and”; and

17 (III) by adding at the end the
18 following:

19 “(E) the submission to the Director of NIH of
20 clinical trial information for the clinical investigation
21 at issue required under section 402(j) of the Public
22 Health Service Act for inclusion in the registry data-
23 base and the results database described in such sec-
24 tion.”;

25 (ii) in paragraph (3)(B)—

1 (I) in clause (i), by striking “or”
2 after the semicolon;

3 (II) in clause (ii), by striking the
4 period at the end and inserting “; or”;
5 and

6 (III) by adding at the end the
7 following:

8 “(iii) clinical trial information for the clinical
9 investigation at issue was not submitted in compli-
10 ance with section 402(j) of the Public Health Service
11 Act.”; and

12 (iii) in paragraph (4), by adding at
13 the end the following: “The Secretary shall
14 update such regulations to require inclu-
15 sion in the informed consent form a state-
16 ment that, if applicable, clinical trial infor-
17 mation for such clinical investigation will
18 be submitted for inclusion in the registry
19 database and results database, if applica-
20 ble, described in section 402(j) of the Pub-
21 lic Health Service Act.”.

22 (B) REFUSAL TO APPROVE APPLICA-
23 TION.—Section 505(d) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 355(d)) is
25 amended—

- 1 (i) in the first sentence, by inserting
2 after “or any particular;” the following:
3 “or (8) the applicant failed to submit the
4 clinical trial information for any clinical
5 trial submitted as part of the application
6 to the Director of the National Institutes
7 of Health in compliance with section 402(j)
8 of the Public Health Service Act;”; and
9 (ii) in the second sentence, by striking
10 “clauses (1) through (6)” and inserting
11 “(1) through (8)”.

12 (c) GUIDANCE.—The Commissioner of Food and
13 Drugs, in consultation with the Director of the National
14 Institutes of Health, shall issue guidance to clarify which
15 clinical trials are applicable clinical trials (as defined in
16 section 402(j)(2)) of the Public Health Service Act, as
17 amended by this section) (42 U.S.C. 282(j)(2)) and are
18 required to be submitted for inclusion in the clinical trial
19 registry database described in such section 402(j)(2).

20 (d) PREEMPTION.—

21 (1) IN GENERAL.—No State or political subdivi-
22 sion of a State may establish or continue in effect
23 any requirement for the registration of clinical trials
24 or for the inclusion of information relating to the re-
25 sults of clinical trials in a database.

1 (2) RULE OF CONSTRUCTION.—The submission
2 of clinical trial information, if submitted in compli-
3 ance with section 402(j) of the Public Health Service
4 Act (as amended by this section) (42 U.S.C. 282(j)),
5 that relates to a use of a drug not included in the
6 labeling of the approved drug shall not be construed
7 by the Secretary or in any administrative or judicial
8 proceeding, as evidence of a new intended use of the
9 drug that is different from the intended use of the
10 drug set forth in the official labeling of the drug.
11 The availability of clinical trial information through
12 the databases under paragraphs (2) and (3) of such
13 section 402(j), if submitted in compliance with such
14 section 402(j), shall not be considered as labeling,
15 adulteration, or misbranding of the drug under the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 301 et seq.).

18 (e) EFFECTIVE DATES.—

19 (1) ESTABLISHMENT OF REGISTRY DATABASE
20 AND RESULTS DATABASE.—Not later than 90 days
21 after the date of enactment of this Act, the Director
22 of NIH shall establish the registry database and the
23 results database of clinical trials of drugs in accord-
24 ance with section 402(j) of the Public Health Service

1 Act (42 U.S.C. 282(j)) (as amended by subsection
2 (a)).

3 (2) CLINICAL TRIALS INITIATED PRIOR TO OP-
4 ERATION OF REGISTRY DATABASE.—The responsible
5 party (as defined in such section 402(j)) for an ap-
6 plicable clinical trial under paragraph (2) of such
7 section 402(j) that is initiated after the date of en-
8 actment of this Act and before the date such reg-
9 istry database is established under paragraph (1) of
10 this subsection, shall submit required clinical trial
11 information not later than 90 days after the date
12 such registry database is established.

13 (3) CLINICAL TRIALS INITIATED AFTER OPER-
14 ATION OF REGISTRY DATABASE.—The responsible
15 party (as defined in such section 402(j)) for an ap-
16 plicable clinical trial under paragraph (2) of such
17 section 402(j) that is initiated after the date such
18 registry database is established under paragraph (1)
19 of this subsection, shall submit required clinical trial
20 information in accordance with such paragraph (2).

21 (4) TRIALS COMPLETED BEFORE OPERATION
22 OF RESULTS DATABASE.—

23 (A) IN GENERAL.—Paragraph (3) of such
24 section 402(j) shall take effect 90 days after
25 the date the results database is established

1 under paragraph (1) of this subsection with re-
2 spect to any applicable clinical trial (as defined
3 in such section 402(j)(3)) that—

4 (i) involves a drug to treat a serious
5 and life-threatening condition; and

6 (ii) is completed between the date of
7 enactment of this section and such date of
8 establishment under paragraph (1) of this
9 subsection.

10 (B) OTHER TRIALS.—Except as provided
11 in subparagraph (A), paragraph (3) of such
12 section 402(j) shall take effect 180 days after
13 the date that the results database is established
14 under paragraph (1) of this subsection with re-
15 spect to any applicable clinical trial (as defined
16 in such section 402(j)(3)) that is completed be-
17 tween the date of enactment of this Act and
18 such date of establishment under paragraph
19 (1).

20 (5) TRIALS COMPLETED AFTER ESTABLISH-
21 MENT OF RESULTS DATABASE.—Paragraph (3) of
22 such section 402(j) shall apply to any applicable
23 clinical trial that is completed after the date that the
24 results database is established under paragraph (1)
25 of this subsection.

1 (6) FUNDING RESTRICTIONS.—Subparagraph
2 (A) of paragraph (4) of such section 402(j) shall
3 take effect 90 days after the date that the clinical
4 trial registry database and the clinical trial results
5 database are established under paragraph (1) of this
6 subsection.

7 (7) STATUS OF CLINICALTRIALS.GOV
8 WEBSITE.—Section 402(j) of the Public Health
9 Service Act (as in effect on the day before the date
10 of enactment of this Act) shall cease to have force
11 or effect upon such date of enactment. The Sec-
12 retary shall maintain an archive of the clinical trials
13 database provided for under such section 402(j) (as
14 in effect on the day before the date of enactment of
15 this Act) on the Internet website of the National Li-
16 brary of Medicine.

17 **TITLE IV—CONFLICTS OF**
18 **INTEREST**

19 **SEC. 401. CONFLICTS OF INTEREST.**

20 (a) IN GENERAL.—Subchapter A of chapter VII of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
22 et seq.) is amended by inserting at the end the following:

23 **“SEC. 712. CONFLICTS OF INTEREST.**

24 “(a) DEFINITIONS.—For purposes of this section:

1 “(1) INVOLVEMENT.—The term ‘involvement’
2 means any financial interest in a product, a com-
3 peting product, in the sponsor of a product, or in
4 the sponsor of a competing product, that may be
5 considered by a panel.

6 “(2) PANEL.—The term ‘panel’ means any
7 committee, board, commission, council, conference,
8 panel, task force, or other similar group, or any sub-
9 committee or other subgroup thereof, that is estab-
10 lished by statute or by the Secretary to provide ad-
11 vice or recommendations to the Secretary regarding
12 activities of the Food and Drug Administration.

13 “(3) PRODUCT.—The term ‘product’ means a
14 food, drug, biological product, device, or electronic
15 product that is regulated by the Food and Drug Ad-
16 ministration.

17 “(b) APPOINTMENTS TO PANELS.—

18 “(1) DISCLOSURE.—Prior to appointment to a
19 panel, each candidate member of a panel shall dis-
20 close to the Secretary all involvements that such
21 candidate may have with the work likely to be un-
22 dertaken by the panel during the term of the ap-
23 pointment for which the candidate is under consider-
24 ation.

1 “(2) EVALUATION AND CRITERIA.—When con-
2 sidering an appointment to a panel, the Secretary—

3 “(A) shall review the potential involve-
4 ments of the candidate for appointment relative
5 to the scope of work likely to be undertaken by
6 the panel during the term of the appointment
7 for which the candidate is under consideration,
8 with the goal of appointing individuals with no
9 involvements, or only potential involvements of
10 low magnitude, with such work, and, to the ex-
11 tent practicable, avoiding the appointment of
12 individuals with potential involvements of high
13 magnitude with such work; and

14 “(B) may appoint 2 or more individuals
15 with similar expertise and non-overlapping or
16 minimally overlapping potential involvements,
17 so as to minimize the likelihood for an ap-
18 pointed individual to require a waiver of a con-
19 flict of interest requirement for service on the
20 panel for a meeting of such panel, or for an ap-
21 pointed individual to be recused from service on
22 the panel for a meeting of such panel.

23 “(c) DISCLOSURE BY PANEL MEMBER.—

24 “(1) IN GENERAL.—Prior to a meeting of a
25 panel, each member of such panel shall disclose to

1 the Secretary all involvements that such member
2 may have with the work to be undertaken by such
3 panel at such meeting.

4 “(2) DETERMINATION BY SECRETARY WITH RE-
5 SPECT TO PANEL MEETINGS.—

6 “(A) IN GENERAL.—The Secretary shall
7 make a determination with respect to each
8 panel member based on the disclosure under
9 paragraph (1). Such a determination shall be in
10 one of the following categories:

11 “(i) APPROVAL FOR SERVICE.—The
12 Secretary shall make the determination of
13 approval for service for a panel member if
14 there is no potential conflict or if the in-
15 volvements of the panel member are a po-
16 tential conflict of low magnitude.

17 “(ii) APPROVAL FOR SERVICE WITH A
18 WAIVER OR LIMITED WAIVER.—The Sec-
19 retary shall make the determination of ap-
20 proval for service with a waiver or limited
21 waiver for a panel member if the involve-
22 ments of the panel member are a potential
23 conflict of medium magnitude and the Sec-
24 retary certifies in writing that—

1 “(I) such waiver is necessary to
2 provide the panel with essential exper-
3 tise; or

4 “(II) the need for the individual’s
5 service outweighs the potential for a
6 conflict of interest created by the dis-
7 closed involvements.

8 “(iii) RECUSAL.—The Secretary shall
9 make the determination of recusal for a
10 panel member if—

11 “(I) any involvement of the panel
12 member is a potential conflict of high
13 magnitude; or

14 “(II) the involvements of the
15 panel member are a potential conflict
16 of medium magnitude but a waiver or
17 limited waiver could not be granted
18 under clause (ii) because the criteria
19 for a certification by the Secretary
20 under such clause were not met.

21 “(B) NOTICE OF DETERMINATION.—

22 “(i) MORE THAN 15 DAYS IN AD-
23 VANCE.—Not later than 15 days prior to a
24 meeting of a panel to which a determina-
25 tion for a panel member under clause (ii)

1 or (iii) of subparagraph (A) applies, the
2 Secretary shall disclose (other than infor-
3 mation exempted from disclosure under
4 section 552 of title 5, United States Code
5 (popularly known as the Freedom of Infor-
6 mation Act)) on the Internet website of the
7 Food and Drug Administration—

8 “(I) the type of the involvements;

9 “(II) the nature of the involve-
10 ments;

11 “(III) the magnitude of the in-
12 volvements; and

13 “(IV) the reasons for any deter-
14 mination of the Secretary under such
15 clause (ii).

16 “(ii) LESS THAN 15 DAYS IN AD-
17 VANCE.—In the case of a conflict of inter-
18 est that becomes known to the Secretary
19 less than 15 days prior to a meeting to
20 which the determination under clause (ii)
21 or (iii) of subparagraph (A) applies, the
22 Secretary shall disclose (other than infor-
23 mation exempted from disclosure under
24 section 552 of title 5, United States Code
25 (popularly known as the Freedom of Infor-

1 mation Act)) on the Internet website of the
2 Food and Drug Administration, the infor-
3 mation described in subclauses (I) through
4 (IV) of clause (i) of this subparagraph as
5 soon as practicable, but in no event later
6 than the date of such meeting.

7 “(d) LIMITATIONS.—In no case—

8 “(1) may the Secretary grant a waiver under
9 subsection (c)(2) for a panel member if the scientific
10 work of such member is under consideration by the
11 panel; or

12 “(2) may a panel member vote with respect to
13 any matter considered by the panel if such panel
14 member or an immediate family member of such
15 panel member could gain financially from the advice
16 given to the Secretary with respect to such matter.

17 “(e) PUBLIC RECORD.—The Secretary shall ensure
18 that the public record of each meeting of a panel includes
19 a description of any determination of the Secretary made
20 under subsection (c)(2), including the category of such de-
21 termination and the involvements of each panel member
22 (other than information exempted from disclosure under
23 section 552 of title 5, United States Code (popularly
24 known as the Freedom of Information Act)).

25 “(f) GUIDANCE.—

1 “(1) NOMINATIONS.—Not later than 270 days
2 after the date of enactment of the Enhancing Drug
3 Safety and Innovation Act of 2006 the Secretary
4 shall publish in the Federal Register for public com-
5 ment a proposed mechanism for encouraging the
6 nomination of individuals that are classified by the
7 Food and Drug Administration as academicians or
8 practitioners for service on any panel.

9 “(2) CONFLICT OF INTEREST DETERMINA-
10 TIONS.—Not later than 270 days after the date of
11 enactment of Enhancing Drug Safety and Innova-
12 tion Act of 2006 the Secretary shall issue or revise
13 guidance—

14 “(A) that defines the circumstances that,
15 taking into consideration the categories of de-
16 termination under subsection (c)—

17 “(i) favor the inclusion of an indi-
18 vidual on a panel;

19 “(ii) favor a waiver of a conflict of in-
20 terest requirement for an individual on a
21 panel;

22 “(iii) favor a limited waiver of a con-
23 flict of interest requirement for an indi-
24 vidual on a panel; and

1 “(iv) disfavor the inclusion of an indi-
2 vidual on a panel;

3 “(B) that gives greater priority to consid-
4 eration of an individual’s net worth over consid-
5 eration of absolute dollar value of an involve-
6 ment in evaluating the magnitude of an involve-
7 ment for purposes of making a determination
8 under subsection (c);

9 “(C) that defines how financial interests
10 imputed to an individual bear upon his or her
11 eligibility for service on a panel or for service
12 at a meeting of a panel;

13 “(D) that clarifies and improves the proc-
14 esses to ensure disclosure of, and to verify the
15 accuracy of, financial interests imputed to an
16 individual; and

17 “(E) to ensure consistency within and
18 among the centers of the Food and Drug Ad-
19 ministration in the issuance of determinations
20 under subsection (c).

21 “(3) PERIODIC REVIEW.—At least once every 5
22 years, the Secretary shall review the guidance de-
23 scribed under paragraph (2) and update such guid-
24 ance as necessary.”.

25 (b) REVIEW BY INSPECTOR GENERAL.—

1 (1) IN GENERAL.—The Inspector General of
2 the Department of Health and Human Services
3 shall, on an ongoing basis, conduct a review of the
4 financial interests of a representative sample of indi-
5 viduals who have served on a panel (as defined in
6 section 712 of the Federal Food, Drug, and Cos-
7 metic Act) (as added by subsection (a)) of the Food
8 and Drug Administration.

9 (2) SUBMISSION OF REPORT.—As part of the
10 semiannual report required under section 5 of the
11 Inspector General Act of 1978 (5 U.S.C. App.), the
12 Inspector General of the Department of Health and
13 Human Services shall include—

14 (A) the results of the review conducted
15 under paragraph (1); and

16 (B) any findings with respect to an indi-
17 vidual being rewarded or otherwise compensated
18 by a sponsor of a product or a sponsor of a
19 competing product for performance as a mem-
20 ber of a panel of the Food and Drug Adminis-
21 tration which considered the product or a com-
22 peting product, or the absence of any such find-
23 ings.

1 (c) CONFORMING AMENDMENT.—Section 505(n) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(n)) is amended by—

4 (1) striking paragraph (4); and

5 (2) redesignating paragraphs (5), (6), (7), and
6 (8) as paragraphs (4), (5), (6), and (7), respectively.

7 (d) EFFECTIVE DATE.—The amendments made by
8 this section shall take effect on October 1, 2007.